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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,071	09/13/2005	Pascal Bernard	0579-1082	5118
466	7590	10/26/2007		
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			EXAMINER MARCETICH, ADAM M	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 10/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/520,071	BERNARD ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05 January 2005</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Priority*

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. France 0208467, filed on 05 July 2002 has been received.

### *Claim Rejections - 35 USC § 102 / 103*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallace (US Patent 5,830,171).

6. Regarding claim 1, Wallace discloses a meatal occluder for closing a lachrymal meatus of a human eye, comprising:

a substantially cylindrical body (column 3, lines 50-54 and Figs. 1-3, shank 13) characterized in that it further comprises:

at least one fin adapted to take up a folded position wherein the fin is substantially folded into the cylindrical body (column 3, lines 55-64 and Fig. 7, wing portion 21 having first collapsed position); and

an extended position wherein the fin projects from the cylindrical body (column 3, lines 64-67 and Fig. 7, wing portion 21 having second expanded position).

When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, a substantially cylindrical body and at least one fin) except for a property or function (in the present case, said fin being heat-deformable from said folded position to said extended position, and the implant being made from a heat-expandable material) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

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7. Regarding claims 2 and 3, Wallace discloses a meatal occluder characterized in that it is made from silicone (column 5, lines 8-13). Examiner notes that silicone is a heat-expandable material, since it is capable of expanding when heated.

8. Regarding claim 4, Wallace discloses the invention as substantially claimed. See above. Wallace discloses an implant comprising silicone as discussed above. The specification of the immediate application discloses silicone as a polymer capable of having a vitreous transition temperature from  $-10^{\circ}\text{C}$  to  $30^{\circ}$  (page 8, lines 11-15).

Therefore, the property of vitreous transition temperature is an intrinsic property of the materials used, and the device of Wallace is capable of having a vitreous transition temperature from  $-10^{\circ}\text{C}$  to  $30^{\circ}\text{C}$ .

9. Regarding claim 5, Wallace discloses a meatal occluder characterized in that said fin pivots between said folded position and said extended position about an axis perpendicular to a longitudinal plane of said meatal occluder (column 4, lines 35-42 and Figs. 7 and 9, wing portion 21 pivoting about axis perpendicular to longitudinal plane of shank 13).

10. Regarding claim 6, Wallace depicts a meatal occluder characterized in that said fin when in said folded position extends in a direction substantially parallel to the longitudinal direction of the cylindrical body (Fig. 7, wing portion 21 extending substantially parallel to shank 13).

11. Regarding claim 7, Wallace depicts a meatal occluder characterized in that said fin is situated in the vicinity of one end of said cylindrical body, a free end of said fin, when in the folded position, extending in the direction of the opposite end of said

cylindrical body (Fig. 9, end of wing portion 21 having folded position extending in direction opposite of shank 13).

12. Regarding claim 9, Wallace discloses a meatal occluder characterized in that said fin is situated in the vicinity of a tapered end of said cylindrical body, the opposite end of said cylindrical body comprising a flange (column 4, lines 22-24 and 43-49; Figs. 2 and 3, flange 23 near nose portion 22).

13. Regarding claim 10, Wallace discloses a meatal occluder characterized in that it comprises a plurality of fins regularly distributed on the cylindrical body of said occluder (column 4, lines 22-24, "wing portion 21 may be formed by a plurality of individual wing elements").

#### ***Claim Rejections - 35 USC § 103***

14. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace (US Patent 5,830,171) in view of Fouere (US Patent 6,254,562).

15. Regarding claim 8, Wallace discloses the invention as substantially claimed. See above. However, Wallace lacks a fin pivoting between a folded position and an extended position about an axis parallel to the longitudinal direction of a cylindrical body as claimed [claim 8]. Fouere discloses a meatal occluder having fins pivoting between a folded position and an extended position about an axis parallel to the longitudinal direction of the cylindrical body (column 2, lines 50-56; Fig. 2, gripping means 12). Fouere provides the advantage of preventing involuntary expulsion of a meatal occluder (column 1, lines 59-64). Therefore, it would have been obvious to one of ordinary skill in

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the art at the time the invention was made to modify the invention of Wallace as discussed with the pivoting fins as taught by Fouere in order to prevent involuntary expulsion of a meatal occluder.

### ***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ❖ Webb et al. (US Patent 6,629,533)
- ❖ Herrick (US Patent 6,149,684)
- ❖ Freeman (US Patent 5,334,137)
- ❖ Herrick (US Patent 5,171,270)
- ❖ Tajiri et al. (US Patent 5,423,777)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich  
Examiner  
Art Unit 3761

*Adam Marcetich*

AMM

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

*Tatyana Zalukaeva*